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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,204	12/21/2001	George L. King	10276-066001	1396

7590

10/07/2002

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,204

Applicant(s)

King

Examiner

Ralph Gitomer

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 21, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

The IDS's received 3/29/02 and 6/20/02 have been entered, claims 1-39 are pending in this application.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ceolotto.

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Ceolotto (Diabetes) entitled ~~Protein Kinase C Activity~~ is Acutely regulated by Plasma Glucose Concentration in Human Monocytes In Vivo ~~teaches~~ teaches on page 1316 column 2, assessing PKC in monocytes may mirror that of vascular cells, the relation between hyperglycemia and PKC activity. On page 1318 column 2, monocytes are a useful model to detect hyperglycemia induced changes in PKC protein content and activity. PKC activity in monocytes may parallel those in other types of cells such as

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vascular cells. Glucose induced alteration in monocyte PKC kinase activity may be relevant to the study of development of diabetic complications and atherosclerosis.

All the features of the claims are taught by Ceolotto for the same function as claimed.

5 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be
15 negated by the manner in which the invention was made.

Claims 16-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ceolotto.

20 Ceolotto (Diabetes) entitled ~~✕~~Protein Kinase C Activity is Acutely regulated by Plasma Glucose Concentration in Human Monocytes In Vivo~~✕~~ teaches on page 1316 column 2, assessing PKC in monocytes may mirror that of vascular cells, the relation between hyperglycemia and PKC activity. On page 1318 column 2, monocytes are a useful model to detect hyperglycemia induced
25 changes in PKC protein content and activity. PKC activity in monocytes may parallel those in other types of cells such as vascular cells. Glucose induced alteration in monocyte PKC kinase activity may be relevant to the study of development of diabetic complications and atherosclerosis.

Claims 16-22 differ from Ceolotto in that they specify evaluating extent, stage, or severity of a disorder. Claims 23-29 differ in that they are directed to evaluating effect of treatment, claims 30-39 are directed to identifying a compound for treating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to diagnose, treat, evaluate treating, identify compounds to treat a disorder after comprehending the mechanism of action of the disorder. Ceolotto discloses a relation between PKC activity in monocytes and hyperglycemic disorders and sequelae. The leap from altering PKC activity to then altering hyperglycemic disorders and sequelae would have been obvious because most presently treated disorders followed the same pattern. For example, once it was understood certain bacteria caused infections, to then alter those bacteria, diagnose infections, treat infections, evaluate the treating and identify compounds to treat followed. No unexpected results are disclosed.

Claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The present claims are directed to a point of novelty including: There is some correlation between PKC activity in monocytes and PKC activity in various cardiovascular tissues. And that PKC activity correlates to some disease states where those disease states (aging?) are treated by administration of therapeutic agents, specifically in humans, is claimed.

No useful data is presented in table form. Fig. 1 shows some correlation between blood glucose level, presumably in human blood serum, and PKC activity in monocytes. Fig. 2 shows a lack of any identifiable correlation between HbA1c level and PKC activity. Fig. 3 suggests there is a correlation between PKC activity in something and diabetic retinopathy. Fig. 4 suggests there is a correlation between PKC activity in something and diabetic nephropathy.

To claim treating humans for a large variety of disorders well known to be difficult to treat by administering something is not enabled by the specification as originally filed. No correlation is seen between PKC activity in monocytes and any other tissue. No correlation is seen between PKC activity in monocytes and ~~the~~ a PKC related disorder~~s~~. No compound is identified for treatment of anything, most particularly aging. No treatment of anything is evaluated by determining PKC activity of anything in any living thing.

Claims 30-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 30 is directed to a method of identifying a compound but appears to be incomplete where a single determination of PKC activity would not be seen to identify a compound. Claim 35 is unclear as to the function of evaluating PKC activity before administration.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: The specification lacks a Brief Description of the Drawings, see page 5. Underlining is queried, see page 7 for example. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (703) 308-4537. The fax phone number for this Art Unit is (703) 308-4556.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business

15 Center for more information.



Ralph Gitomer
Primary Examiner
Group 1627

**RALPH GITOMER
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